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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on October 21, 2008 is acknowledged. Claims 1 and 12 have been amended. Claims 25-27 have been canceled. Claims 1-6, 8-10 and 12-24 are currently pending and under examination.

Rejections Withdrawn

1. In view of Applicant's arguments, the rejection of claims 1-6, 8-10 and 12-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. The cancellation of claims 25-27 renders the rejection of said claims moot.

2. In view of Applicant's arguments, the rejection of claims 1-6, 8-10 and 12-27 under 35 U.S.C. 112, second paragraph, as being indefinite for the use of the phrase "wherein the botulinum toxin administered is less than the amount used to paralyze a muscle" is withdrawn. The cancellation of claims 25-27 renders the rejection of said claims moot.

Rejections Maintained

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The rejection of claims 1-6, 8-10 and 12-21 under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893 A1), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPI.pdf, accessed on March 22, 2007) is maintained for the reasons set forth in the previous Office action. The cancellation of claims 25-27 renders the rejection of said claims moot.

Applicant argues that:

1) Kwon does not disclose delivery of botulinum toxin with a needle.

2) Kwon's matrix to be delivered is a solid.

3) Kwon does not teach or suggest delivery of a non-paralytic amount of botulinum toxin.

Applicant's arguments have been considered, but have not been deemed persuasive.

The claims are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection with a needle per session; wherein the skin disorder comprises a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion; and wherein the botulinum toxin administered is less than the amount used to paralyze a muscle.

With regard to Point 1, contrary to Applicant's arguments, Kwon discloses a system which includes an array of one or more needles (see paragraph 0010). Figures 1 and 2 clearly demonstrate that the needle of Kwon encompasses intradermal or subdermal injection. When giving the instant claims, particularly the limitation of "injection with a needle", their broadest reasonable interpretation, the limitation of needle is meet by the disclosure of Kwon.

With regard to Point 2, the instant claims are drawn to a method that comprises the step of administering botulinum toxin to a patient to treat a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion. Kwon discloses a method of treating corns, warts, calluses, bunions and keratoses comprising administering a therapeutically effective amount of botulinum toxin. While the Kwon reference discloses the use of a SSP (which uses needles, blades or other perforators), at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution. Although Kwon uses a SSP, perforators by definition (i.e. to pierce or penetrate) meet the limitation of the instant claims.

With regard to Point 3, while Kwon may not explicitly disclose that botox is to be administered in non-paralytic or paralytic amounts, the methods of the instant invention and Kwon are identical. Claim 1 is drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin

disorder; wherein the solution is administered by intradermal injection or subdermal injection with a needle per session; wherein the skin disorder comprises a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion; and wherein the botulinum toxin administered is less than the amount used to paralyze a given muscle. Applicant submits that one of ordinary skill in the art would be able to determine what amount of botulinum toxin to be administered is a non-paralyzing amount for a muscle (see page 11 of Applicant's Arguments filed 10/21/08). Consequently, based on Applicant's submission and absent evidence to the contrary, Kwon necessarily administers an amount of botulinum toxin which is less than the amount used to paralyze a muscle.

As previously presented, Kwon discloses a method of administering a safe and effective amount of botulinum toxin for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions and keratoses (see page 6, paragraph 0077). Moreover, Kwon discloses administering the botulinum toxin via a patch (topical). Kwon discloses that a design of an SSP patch includes an array of perforators that is porous and optionally serves as a drug reservoir and the active ingredients are contained in the perforator. Kwon discloses that the design is ideal for potent drug delivery, for administering small doses systemically, or for topical applications (see page 5, paragraph 0049).

The instant specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (see page 21), inherently Kwon has administered a therapeutically amount of botulinum toxin. With regard to claims 8-10,

due to the mode of action of botulinum toxin its administration would necessarily reduce a pain and/or inflammation associated with the skin disorder as well as reduce the size of a disorder selected from the group consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two toes, hammertoes and bunions. Moreover, in view of all disclosed above the method necessarily encompasses intradermal or subdermal injection as well as a topical wherein the composition is a cream or lotion.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

4. Claims 1-6, 8-10 and 12-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 1 and 12 to recite "injection with a needle...". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Applicant points to paragraph (0044) of the instant U.S. published application for support for said amendment. However, paragraph (0044) only discloses that controlled release toxin implants are known as transdermal botulinum toxin administration.

To overcome this rejection Applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

Conclusion

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
1/29/09

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645